K081537

JAN 22 2009

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: Angel L Fernandez dba Comfort and Flexible Systems
2-Address: 8223 Santa Fe Spring Road
Whittier, CA 90606
3-Phone: 562 693 3858
4-Fax: 562 745 5607
5-Contact Person: Mr Angel L Fernandez (President)
6-Date summary prepared: May 16th, 2008
7- Official Correspondent: Mansour Consulting LLC
8- Address: 845 Aronson Lake Court. Roswell, GA 30075 USA
9- Phone: 678-908-8180
10- Fax: 678-623-3765
11- Contact Person: Jay Mansour, President

12-Device Trade or Proprietary Name: CFS FLEXIBLE™

13-Device Common or usual name: Denture Relining, Repairing, or Rebasing resin

14-Device Classification Name: Denture Relining, Repairing, or Rebasing resin

15-Substantial Equivalency is claimed against TCS® Unbreakable, cleared under K053060

16-Description of the Device:
CFS FLEXIBLE™ is an injection moldable, flexible, thermoplastic nylon with trace amounts of colorant added.
CFS FLEXIBLE™ is used for fabricating removable dental prosthetic appliances such as full and partial dentures, orthodontics devices, occlusal splints and night guards both permanent and temporary. Because it can be used to create completely non-metallic prosthetics, it is perfect for making removable dental prosthetic appliances for metal-allergic patients.

17-Intended use of the device: (refer to FDA form attached)

CFS FLEXIBLE™ is a break resistant material used in the fabrication and repair of base plates for removable dental prosthetic appliances where superior flexibility and patient comfort for the lifetime of the prosthetic are significant concerns. This includes, but not limited to, full and partial dentures, orthodontic devices, occlusal splints, and night guards.

18-Safety and Effectiveness of the device:

CFS FLEXIBLE™ is safe and effective as the predicate device cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2009

Angel L Fernandez dba Comfort and Flexible Systems
C/O Mr Jay Mansour
President
Mansour Consulting, L L C
845 Aronson Lake Court
Roswell, Georgia 30075

Re K081537
Trade/Device Name CFS FLEXIBLE™
Regulation Number 21 CFR 872 3760
Regulation Name Denture Relining, Repairing, or Rebasing Resin
Regulatory Class II
Product Code EBI
Dated December 8, 2008
Received January 21, 2009

Dear Mr Mansour

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Anthony D. Watson for
Ginette Y Michaud, M D
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K081537

Device Name CFS FLEXIBLE™

Indications For Use

CFS FLEXIBLE™ is a break resistant material used in the fabrication and repair of base plates for removable dental prosthetic appliances where superior flexibility and patient comfort for the lifetime of the prosthetic are significant concerns This includes, but not limited to, full and partial dentures, orthodontic devices, occlusal splints, and night guards

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number K081537